



General

Guideline Title

Follow-up for clinically localized renal neoplasms: AUA guideline.

Bibliographic Source(s)

Donat SM, Diaz M, Bishoff JT, Coleman JA, Dahm P, Derweesh IH, Herrell SD III, Hilton S, Jonasch E, Lin DW, Reuter VE, Chang SS. Follow-up for clinically localized renal neoplasms: AUA guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2013 Apr. 33 p. [135 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the body of evidence strength (grade A, B, or C), the strength of the recommendations (Standard, Recommendation, Option), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Guideline Statements

- 1. Patients undergoing follow-up for treated or observed renal masses should undergo a history and physical examination directed at detecting signs and symptoms of metastatic spread or local recurrence. (*Clinical Principle*)
- 2. Patients undergoing follow-up for treated or observed renal masses should undergo basic laboratory testing to include blood urea nitrogen (BUN)/creatinine, urine analysis (UA) and estimated glomerular filtration rate (eGFR). Other laboratory evaluations, including complete blood count (CBC), lactate dehydrogenase (LDH), liver function tests (LFTs), alkaline phosphatase (ALP) and calcium level, may be used at the discretion of the clinician. (*Expert Opinion*)
- 3. Patients with progressive renal insufficiency on follow-up laboratory evaluation should be referred to nephrology. (Expert Opinion)
- 4. The Panel recommends a bone scan in patients with an elevated ALP, clinical symptoms such as bone pain, and/or if radiographic findings are suggestive of a bony neoplasm. (*Recommendation*; Evidence Strength: Grade C)
- 5. The Panel recommends against the performance of a bone scan in the absence of an elevated ALP or clinical symptoms, such as bone pain, or radiographic findings suggestive of a bony neoplasm. (*Recommendation*; Evidence Strength: Grade C)
- 6. Patients with a history of a renal neoplasm presenting with acute neurological signs or symptoms must undergo prompt neurologic cross-sectional computed tomography (CT) or magnetic resonance imaging (MRI) scanning of the head or spine based on localization of symptomatology. (Standard; Evidence Strength: Grade A)
- 7. The Panel recommends against the routine use of molecular markers, such Ki-67, p-53 and vascular endothelial growth factor (VEGF), as

Surgery: Low Risk Patients (pT1, N0, Nx)

- 8. Patients should undergo a baseline abdominal scan (CT or MRI) for nephron sparing surgery and abdominal imaging (ultrasound [US], CT or MRI) for radical nephrectomy within three to twelve months following renal surgery. (*Expert Opinion*)
- 9. Additional abdominal imaging (US, CT or MRI) may be performed in patients with low risk (pT1, N0, Nx) disease following a radical nephrectomy if the initial postoperative baseline image is negative. (*Option*; Evidence Strength: Grade C)
- 10. Abdominal imaging (US, CT, or MRI) may be performed yearly for three years in patients with low risk (pT1, N0, Nx) disease following a partial nephrectomy based on individual risk factors if the initial postoperative scan is negative. (*Option*; Evidence Strength: Grade C)
- 11. The Panel recommends that patients with a history of low risk (pT1, N0, Nx) renal cell carcinoma undergo yearly chest x-ray (CXR) to assess for pulmonary metastases for three years and only as clinically indicated beyond that time period. (*Recommendation*; Evidence Strength: Grade C)

Surgery: Moderate to High Risk Patients (pT2-4N0 Nx or Any Stage N+)

- 12. The Panel recommends that moderate to high risk patients undergo baseline chest and abdominal scan (CT or MRI) within three to six months following surgery with continued imaging (US, CXR, CT or MRI) every six months for at least three years and annually thereafter to year five. (*Recommendation*; Evidence Strength: Grade C)
- 13. The Panel recommends site-specific imaging as warranted by clinical symptoms suggestive of recurrence or metastatic spread. (*Recommendation*; Evidence Strength: Grade C)
- 14. Imaging (US, CXR, CT or MRI) beyond five years may be performed at the discretion of the clinician for moderate to high risk patients. (*Option*; Evidence Strength: Grade C)
- 15. Routine fludeoxyglucose positron emission tomography (FDG-PET) scan is not indicated in the follow-up for renal cancer. (*Expert Opinion*)

Active Surveillance

- 16. Percutaneous biopsy may be considered in patients planning to undergo active surveillance. (Option; Evidence Strength: Grade C)
- 17. The Panel recommends that patients undergo cross-sectional abdominal scanning (CT or MRI) within six months of active surveillance initiation to establish a growth rate. The Panel further recommends continued imaging (US, CT or MRI) at least annually thereafter. (*Recommendation*; Evidence Strength: Grade C)
- 18. The Panel recommends that patients on active surveillance with biopsy proven renal cell carcinoma or a tumor with oncocytic features undergo an annual CXR to assess for pulmonary metastases. (*Recommendation*; Evidence Strength: Grade C)

Ablation

- 19. A urologist should be involved in the clinical management of all patients undergoing renal ablative procedures including percutaneous ablation. (*Expert Opinion*)
- 20. The Panel recommends that all patients undergoing ablation procedures for a renal mass undergo a pretreatment diagnostic biopsy. (*Recommendation*; Evidence Strength: Grade C)
- 21. The standardized definition of "treatment failure or local recurrence" suggested in the Clinical T1 Guideline document should be adopted by clinicians. This should be further clarified to include a visually enlarging neoplasm or new nodularity in the same area of treatment whether determined by enhancement of the neoplasm on post-treatment contrast imaging, or failure of regression in size of the treated lesion over time, new satellite or port site soft tissue nodules, or biopsy proven recurrence. (*Clinical Principle*)
- 22. The Panel recommends that patients undergo cross-sectional scanning (CT or MRI) with and without intravenous (IV) contrast unless otherwise contraindicated at three and six months following ablative therapy to assess treatment success. This should be followed by annual abdominal scans (CT or MRI) thereafter for five years. (*Recommendation*; Evidence Strength: Grade C)
- 23. Patients may undergo further scanning (CT or MRI) beyond five years based on individual patient risk factors. (*Option*; Evidence Strength: Grade C)
- 24. Patients undergoing ablative procedures who have either biopsy proven low risk renal cell carcinoma, oncocytoma, a tumor with oncocytic features, nondiagnostic biopsies or no prior biopsy, should undergo annual CXR to assess for pulmonary metastases for five years. Imaging beyond five years is optional based on individual patient risk factors and the determination of treatment success. (*Expert Opinion*)
- 25. The Panel recommends against further radiologic scanning in patients who underwent an ablative procedure with pathological confirmation of benign histology at or before treatment and who have radiographic confirmation of treatment success and no evidence of treatment related complications requiring further imaging, (*Recommendation*; Evidence Strength: Grade C)
- 26. The alternatives of observation, repeat treatment and surgical intervention should be discussed, and repeat biopsy should be performed if

- there is radiographic evidence of treatment failure within six months if the patient is a treatment candidate. (Expert Opinion)
- 27. A progressive increase in size of an ablated neoplasm, with or without contrast enhancement, new nodularity in or around the treated zone, failure of the treated lesion to regress in size over time, satellite or port side lesions, should prompt lesion biopsy. (*Expert Opinion*)

Definitions:

Body of Evidence Strength

Overall quality scores together with study design and consistency of estimates across studies were used to grade the strength of the evidence into three levels: A (high), B (moderate) or C (low).

American Urological Association (AUA) Nomenclature Linking Statement Type to Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A or B evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C evidence

Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A, B, or C evidence

Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Localized renal neoplasms

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Family Practice

Nephrology

Oncology

Radiology

Urology

Intended Users

Physicians

Guideline Objective(s)

To create evidence-based guidelines for the follow-up and surveillance of clinically localized renal cancers treated with surgery or renal ablative procedures, biopsy-proven untreated clinically localized renal cancers followed on surveillance and radiographically suspicious but biopsy-unproven renal neoplasms either treated with renal ablative procedures or followed on active surveillance

Note: These guidelines are not meant to address hereditary or pediatric kidney cancers, although they must take into account that a proportion of adult patients may harbor a yet unrecognized hereditary form of renal cancer.

Target Population

Adults with of one of the following:

- Clinically localized renal cancers treated with surgery or renal ablative procedures
- Biopsy-proven untreated clinically localized renal cancers followed on surveillance
- Radiographically suspicious but biopsy-unproven renal neoplasms either treated with renal ablative procedures or followed on active surveillance

Interventions and Practices Considered

- 1. Patient history and physical examination
- 2. Laboratory testing
 - Blood urea nitrogen (BUN)/creatinine
 - Urine analysis (UA)
 - Estimated glomerular filtration rate (eGFR)
 - Complete blood count (CBC)
 - Lactate dehydrogenase (LDH)
 - Liver function tests (LFTs)
 - Alkaline phosphatase (ALP)
 - Calcium level

Note: Routine use of molecular markers, such as Ki-67, p-53, and vascular endothelial growth factor (VEGF), was considered but not recommended

- 3. Referral to nephrology
- 4. Imaging
 - Abdominal computed tomography (CT) or magnetic resonance imaging (MRI), ultrasound (US)
 - Bone scan
 - Neurologic cross-sectional CT or MRI scanning of the head or spine, as indicated
 - Chest x-ray (CXR)
 - Site specific imaging (as indicated)

Note: The routine use of fludeoxyglucose positron emission tomography (FDG-PET) is not recommended in the follow-up for renal cancer.

- 5. Percutaneous biopsy
- 6. Surgery (nephron sparing, radical nephrectomy)
- 7. Renal ablative procedures including percutaneous ablation

Major Outcomes Considered

- · Sensitivity, specificity, and accuracy of diagnostic tests
- Incidence and rate of tumor growth
- Incidence and severity of renal impairment
- Incidence of:
 - Local recurrence
 - Secondary tumor
- Metastasis
- Mortality

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic review was conducted to identify published articles relevant to key questions specified by the Panel (see Appendix B [see the "Availability of Companion Documents" field]) related to kidney neoplasms and their follow-up (imaging, renal function, markers, biopsy, prognosis). The search of the PubMed, Embase and Cochrane databases covered articles in English published between January 1999 and 2011. An updated query was later conducted to include studies published through August 2012. Study designs consisting of clinical trials (randomized or not), observational studies (cohort, case-control, case series) and systematic reviews were included. All other study types were excluded. Studies with full-text publication available were included, but studies in abstract form only were excluded.

This literature included studies that focused on patients diagnosed with clinically localized, histologically proven renal cell carcinoma; clinically localized oncocytoma or cystic nephroma; radiographically suspicious, solid neoplasms or suspicious/complex cystic neoplasms without biopsy and neoplasms radiographically consistent with angiomyolipoma. Patients with metastatic renal cell carcinoma, transitional cell carcinoma and hereditary syndromes as well as those treated with radiation or systemic therapy were excluded. Additionally, studies involving pediatric patients or those in which outcomes among qualifying index cases could not be separated from other cases or other malignancies were excluded as well. Management strategies considered include active surveillance, surgery (partial or radical nephrectomy) and ablative procedures (cryoablation or radiofrequency ablation). In terms of interventions, inclusion criteria incorporated studies involving follow-up regimens evaluating oncologic and functional outcomes using imaging and/or lab measurements and/or physical examination and/or biopsy. All other management strategies or treatment itself were excluded. Studies with less than 30 patients were excluded given the unreliability of the statistical estimates and conclusions that can be derived from them.

Articles with abstracts fulfilling the outlined inclusion criteria that addressed one or more of the posed questions were retrieved in full text for further review. Reason for exclusion of rejected articles was recorded. Studies reported within multiple publications were scrutinized in order to retrieve the most recent, non-redundant and inclusive data. Related references contained in each article were perused to ensure the inclusion of all pertinent material.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Delphi Method)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Overall quality scores together with study design and consistency of estimates across studies were used to grade the strength of the evidence into three levels: A (high), B (moderate) or C (low).

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Accepted articles were extracted using customized forms. Given the pool size of eligible articles, independent double extraction was not possible for most articles. Instead, the methodologist reviewed the work of the extractors and searched for inconsistencies and missing information in the data extracted with emphasis on outcomes.

The methodological quality of the studies was evaluated using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool for questions framed in the context of a "diagnostic" problem. Many studies included retrospective cohorts reporting on the follow-up of patients. For these studies, the framework proposed by Hayden et al. was used to assess their methodological quality. This framework evaluates potential sources of bias within six domains: sample representativity, attrition, adequate measurement of prognostic factors, adequate measurement of outcomes, assessment and control of potential confounders and appropriate statistical analysis. This framework's implementation was adapted to the question context. Overall quality scores together with study design and consistency of estimates across studies were used to grade the strength of the evidence into three levels: A (strong), B (moderate) and C (weak).

Descriptive statistics of study characteristics were calculated to identify potential study outliers that could signal data extraction problems and/or influential studies. These were also used to identify factors that could explain heterogeneity of estimates, if found. Meta-analyses were performed on questions in which at least four studies were available. These estimates were based on DerSimonian-Laird random effects. Meta-regression was performed when heterogeneity was encountered and enough studies were available to examine at least one predictor at a time. Heterogeneity was considered present if the inconsistency I² statistic was above 25% or when the forest plot showed a potential mixture of outcomes if a small number of studies were available. Analyses were performed in the R platform version 2.12.0 for Windows and the code *meta*.

For most outcomes, a meta-analysis of proportions was performed. For these, raw counts for numerator and denominator were extracted from each study. The other meta-analyses were performed on the hazard rate (survival after surgery), hazard ratio (from multivariable Cox regression models) and area under the characteristic (AUC) curve and their corresponding standard error.

Hazard rates were obtained from survival rates at a minimum of five years, assuming that the curve exhibited an exponential distribution. The assumption of an exponential distribution could be confirmed graphically from a group of articles that provided corresponding survival curves. The resulting overall hazard rate was used to build a cumulative incidence function that covered five years of follow-up. The proportion of events in quarters for the first two years and biannually for the following three years were determined in order to guide the selection of an appropriate follow-up frequency for cases of clinically localized renal mass undergoing curative surgery without adjuvant or salvage treatment. Since partial and radical nephrectomy have been considered equivalent in terms of cancer control outcomes for T1 disease, these were included in the same analysis to increase the number of studies available.

The standard error was estimated from available data when it was not provided directly by the individual studies. In the case of survival curves, Kaplan-Meier curves with number of individuals at risk were transformed to their corresponding standard error. In the case of the AUC, actual numbers of individuals diseased and non-diseased and numbers of individuals labeled as diseased and non-diseased by a threshold were used for determining the standard error as proposed by Hanley and McNeil. AUC was used for assessing kidney function, and disease refers to patients

with kidney insufficiency. When standard error was not available or could not be estimated the study was excluded from analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The Follow-up for Clinically Localized Renal Neoplasms Panel was created by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel Chair and Vice Chair who in turn appointed the additional panel members, all of whom have demonstrated a specific expertise with regard to the guideline subject. For some clinical issues, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of Clinical Principles or Expert Opinions with consensus achieved using a modified Delphi technique if differences of opinion existed among Panel members.

Rating Scheme for the Strength of the Recommendations

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Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) conducted an extensive peer review process. The initial draft of this Guideline was distributed to 67 peer reviewers; 39 responded with comments. The Panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the Guideline was submitted for approval to the Practice Guidelines Committee (PGC). It was then submitted to the AUA Board of Directors for final approval.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for most treatment recommendations (see the "Major Recommendation" field). Where evidence was lacking, recommendations are supported by expert opinion or consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of patients with clinically localized renal neoplasms

Potential Harms

- Despite the advantages of computed tomography (CT) and magnetic resonance imaging (MRI), the potential adverse effects and cost should also be kept in mind. Recent attention has been paid to the cumulative radiation exposure of the population attributable to the widespread and increasing use of CT scanning. There is some indirect evidence linking exposure to low-level ionizing radiation at doses used in CT to subsequent development of cancer.
- Although the true risk of cancer development from exposure to diagnostic radiation for a given individual from CT is not known, it is prudent
 to limit use of CT to those clinical indications in which the benefit is felt to outweigh the risk. In addition, risks related to administration of
 iodinated intravenous (IV) contrast for CT, including contrast hypersensitivity and contrast-induced renal failure, should also be kept in mind
 when considering the use of CT in the workup and follow-up of renal cancer.
- For MRI, which does not involve the use of ionizing radiation, the prime adverse effect to consider is the development of nephrogenic systemic fibrosis (NSF) due to IV gadolinium administration.
- Unless the diagnostic information is essential and not available with MRI performed without IV contrast, the U.S. Food and Drug
 Administration (FDA) currently recommends against the use of gadolinium-based contrast agents in patients with acute or chronic renal
 insufficiency, with a glomerular filtration rate (GFR) less than 30 mL per minute per 1.73 m² or with any acute renal failure caused by the
 hepatorenal syndrome or perioperative liver transplantation.
- Patients should be counseled about the small but potential risk of cancer progression while on active surveillance, the potential loss of a
 window of opportunity for nephron-sparing surgery, the lack of curative salvage therapies if metastases develop and the deficiencies of the
 current data used to support this approach.

Contraindications

Contraindications

In circumstances of declining renal function, contrast enhanced studies are contraindicated.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Urological Association Education and Research, Inc.
 (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated.
 As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any
 clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain

drug uses ("off label") that are not approved by the U. S. Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not in-tended to provide legal advice about use and misuse of these substances.

- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of
 close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or
 management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.
- For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily
 experimental or investigational.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Donat SM, Diaz M, Bishoff JT, Coleman JA, Dahm P, Derweesh IH, Herrell SD III, Hilton S, Jonasch E, Lin DW, Reuter VE, Chang SS. Follow-up for clinically localized renal neoplasms: AUA guideline. Linthicum (MD): American Urological Association Education and Research, Inc.; 2013 Apr. 33 p. [135 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Apr

Guideline Developer(s)

American Urological Association Education and Research, Inc. - Medical Specialty Society

Source(s) of Funding

American Urological Association, Inc. (AUA)

Guideline Committee

Follow-up for Clinically Localized Renal Neoplasms Panel

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Financial Disclosures/Conflicts of Interest

Committee members received no remuneration for their work. All panel members completed conflict of interest (COI) disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

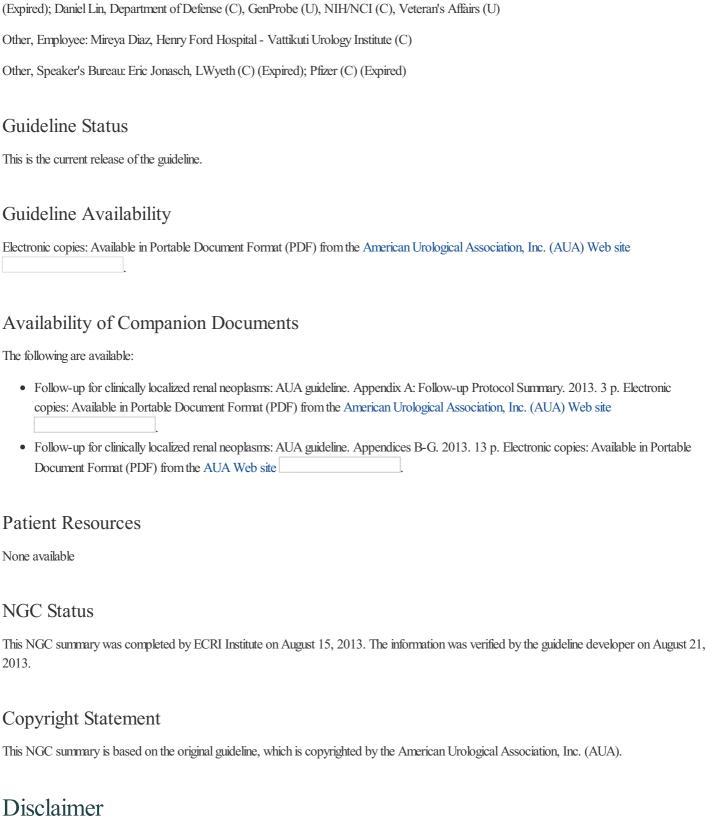
Board Member, Officer or Trustee: Victor E. Reuter, United States and Canadian Academy of Pathology (U) (Expired)

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Investment Interest: S. Duke Herrell, Veran Medical Technologies (U)

Scientific Study or Trial: Jay Todd Bishoff, Pfizer (C); Jonathan Coleman, Steba (U); Philipp Dahm, CureVac (C) (Expired); S. Duke Herrell, Galil Medical (C), Wilex (C) (Expired); Eric Jonasch, Aveo (C), Bristol Myers Squibb (C), Glaxo Smith Kline (C), Novartis (C), Pfizer (C)



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